MAY - 4 2004

K040146

ATTACHMENT 8

SUMMARY OF SAFETY AND EFFECTIVENESS

STATEMENT OF STAFETY AND EFFECTIVENESS

The sponsor, InterLab srl. has developed, manufactured, and tested under Good Laboratory Practices guidelines, in vitro diagnostic (IVD) devices for qualitative identification of abnormal hemoglobin fractions for the electrophoretic separation of whole blood. The device trade name is the InterLab Acid Hemoglobin Electrophoresis having FDA assigned name: Electrophoretic Abnormal Hemoglobin Analysis systems, and a classification as a Class II device per 21 CFR Sec. 864.7415, with product code: GKA.

The InterLab Acid Hemoglobin test kits for the electrophoretic separation of hemoglobin in whole blood and are intended for *In-Vitro* diagnostic use only. The InterLab Acid Hemoglobin Electrophoresis Test Devices provide qualitative identification of abnormal hemoglobin bands visualized by staining of the fractions. The principle of hemoglobin electrophoresis is based upon the visualization of specific hemoglobin bands following separation by electrophoresis. Dilutions of a patient's specimen are placed on separate tracks (fingers) on a cellulose acetate slide six fingers shaped, and the major hemoglobin groups are separated by electrophoresis. The migration rate depends on the temperature, pH, ionic force of the solution and proportions of the reactants. After electrophoresis, the slide is processed to remove excess soluble materials through a washing step. Fractionated hemoglobins are stained. The excess of stain is removed by a destaining step. The slides visually read to identify the bands present.

Studies were performed using samples from both normal and suspected pathological patients submitted for routine testing to the clinical or hospital laboratory. The studies were run at 2 facilities and the samples were tested with the InterLab Acid Hemoglobin test system run on the Microtech instrument and compared to the laboratory's routine commercially available test system following the laboratory's procedure.

Standard procedure at site one for Acid Hb is based on the qualitative evaluation of the electrophoretic results, when HPLC analysis of blood samples displays values of hemoglobin fractions that are outside the reference ranges (HbA2, HbF) or indicates the presence of abnormal fractions, electrophoresis is required as an additional confirmatory test. Abnormal results obtained by HPLC analysis, including either elevated concentration of normal hemoglobins (*e.g.* HbA2 or HbF) or appearance of variants, namely hemoglobins not normally present in red blood cells (*e.g.* HbS), require further investigation to assess the type of additional Hemoglobin(s) present in the sample.

Site two uses a commercially available Alkaline Hemoglobin Electrophoresis system to screen the patient samples. Fractions identified as potentially abnormal are run on the Acid Hemoglobin test for confirmation. Comparison was accomplished exclusively by visual inspection of the electrophoretic patterns. Complete agreement between the two systems was obtained.

The InterLab Acid Hemoglobin test demonstrated equivalent band patterns to the reference tests with no false negative or false positive bands observed by visual inspection for the seventy-one (71) normal and pathological samples evaluated. This study resulted in a 100% agreement to the reference methods for the observed bands at both sites. These results demonstrate that the InterLab Acid Hemoglobin test system is substantially equivalent to the commercially available reference tests.

Analytical Sensitivity

The InterLab Hemoglobin Test systems will detect hemoglobin bands at concentrations greater than 2.4 g/L for HbA, 1.9 g/L for Hb F, 1.6 g/L for HbS, and 1.54 g/L for HbC. Samples were serially diluted and run on the InterLab method. The patterns were visually inspected to see

when the bands were no longer visible. That sample's dilution was back calculated to determine its concentration.

Precision (Within Slide)
Three different serum samples were run in replicate on single slide for each instrument system. The patterns were visually inspected and found to be qualitatively identical. In each lane the bands were correctly identified. No false fractions or aberrations were observed. The following typical results were obtained for the kits.

SRE158K

SAMPLE	N.	Detected bands
B	12	HbF, HbA, HbC
C	12	HbA, HbC
A	12	HbF, HbA, HbS

SRE164K

SAMPLE	N.	Detected bands
AA	8	HbA-HbS
BB	8	HbF-HbA
CC	8	HbA-HbC

Precision (Slide to Slide)
Three different serum samples were run in triplicate on multiple separate slides for each instrument system. The patterns were visually inspected and found to be qualitatively identical. In each lane the bands were correctly identified. No false fractions or aberrations were observed. The following typical results were obtained for the kits.

SRE158K

SAMPLE	N.	Detected bands
A	30	HbF, HbA, HbS, HbC
S	30	HbA, HbS
F	30	HbF, HbA

SRE164K

SAMPLE	N.	Detected bands
XX	33	HbF, HbA1, HbS, HbC
YY	33	HbF, HbA
ZZ	36	HbA, HbS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY - 4 2004

InterLab S.R.L.
Mr. Gary Lehnus
Trouble Shooter Consulting, Inc.
150 Cherry Lane Road
East Stroudsburg, PA 18301

Re: k040146
Trade/Device Name: Interlab Acid Hemoglobin Test Systems By Eletrophoresis
Regulation Number: 21 CFR 864.7415
Regulation Name: Abnormal Hemoglobin assay
Regulatory Class: Class II
Product Code: GKA
Dated: March 30, 2004
Received: April 9, 2004

Dear Mr. Lehnus:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Joseph L. Hackett

Joseph L. Hackett, Ph.D.
Acting Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K040146

Device Name: Interlab Acid Hemoglobin Test Systems

by Electrophoresis

Indications For Use:

The Interlab Acid Hemoglobin Electrophoresis is a qualitative test system intended for the electrophoretic separation of hemoglobins to confirm the identity of clinically relevant hemoglobins such as A, F, S and C. It is to be used in conjunction with the Interlab Alkaline Hemoglobin Electrophoresis test kit. The Acid Hemoglobin test kit employs cellulose acetate supported on Mylar® as the medium and is for *in vitro* diagnostic use. The test can be automated on the Microtech 672 PC and Microtech 648 ISO instruments.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K040146

Prescription Use: X
(Per 21 CFR 801.109)

OR **Over-The-Counter Use:** _____
(Optional Format 1-2-96)